This following listing of claims is being provided for the Examiner's convenience. The following listing of claims includes the currently pending claims.

II. Listing of Claims:

Claim 1. (Previously presented) An oral dosage form, comprising an orally therapeutically effective amount of

(A) an opioid agonist,

(B) acetaminophen, and

(C) an opioid antagonist; the dosage form having a ratio of opioid antagonist to opioid agonist to acetaminophen that provides a combination product which is analgesically effective when the combination is administered orally, but which (i) is aversive in physically dependent human subjects when administered in the same amount and in a higher amount than said therapeutically effective amount; and (ii) maintains an analgesic effect but does not increase analgesic efficacy of the opioid agonist together with the acetaminophen relative to the same therapeutic amount of opioid analgesic together with the acetaminophen when administered to human patients without said opioid antagonist.

Claim 2. (Cancelled)

Claim 3. (Previously Presented) The oral dosage form of claim 1, wherein the opioid agonist is hydrocodone or a pharmaceutically acceptable salt thereof and the antagonist is naltrexone or a pharmaceutically acceptable salt thereof.

Claims 4-7 (Cancelled)

Claim 8. (Previously presented) The oral dosage form of claim 1, further comprising a sustained release carrier that causes said opioid agonist to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

Claim 9. (Previously presented) The oral dosage form of claim 1, wherein said opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephene, cyclazocine, levallorphan, pharmaceutically acceptable salts thereof and mixtures thereof.

Claim 10. (Previously presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof.

Claim 11. (Cancelled)

Claim 12. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is oxycodone or a pharmaceutically acceptable salt thereof.

Claim 13. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is codeine or a pharmaceutically acceptable salt thereof.

Claim 14. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is hydromorphone or a pharmaceutically acceptable salt thereof.

Claim 15. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is levorphanol or a pharmaceutically acceptable salt thereof.

Claim 16. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is meperidine or a pharmaceutically acceptable salt thereof.

Claim 17. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is methadone or a pharmaceutically acceptable salt thereof.

Claim 18. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is morphine or a pharmaceutically acceptable salt thereof.

Claim 19. (Previously presented) The oral dosage form of claim 8, wherein the sustained release carrier further causes said opioid antagonist to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

Claim 20. (Previously presented) The oral dosage form of claim 8, wherein the sustained release carrier further causes the acetaminophen to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

Claim 21. (Original) The oral dosage form of claim 1, wherein the dose of opioid agonist would be subtherapeutic if administered without the acetaminophen.

Claim 22. (Original) The oral dosage form of claim 1, wherein the dose of acetaminophen would be subtherapeutic if administered without the opioid agonist.

Claim 23. (Original) The oral dosage form of claim 1, wherein the amount of acetaminophen included in the dosage form is from about 10 mg to about 2000 mg.

Claim 24. (Original) The oral dosage form of claim 1, wherein the amount of acetaminophen included in the dosage form is from about 25 mg to about 1000 mg.

Claim 25. (Original) The oral dosage form of claim 1, wherein the amount of acetaminophen included in the dosage form is from about 325 mg to about 1000 mg.

Claim 26. (Previously presented) The oral dosage form of claim 1, wherein the opioid agonist and the acetaminophen would each be subtherapeutic if not used in combination with each other.

Claim 27. (Previously presented) The oral dosage form of claim 8, wherein said sustained release carrier causes said antagonist and said acetaminophen to be released over a time period of about 8 to about 24 hours when the dosage form is orally administered to a human patient.

Claim 28. (Cancelled)

Claim 29. (Previously presented) The oral dosage form of claim 1, wherein said opioid agonist is selected from the group consisting of morphine, hydromorphone, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine, tramadol, pharmaceutically acceptable salts thereof and mixtures thereof.

Claim 30. (Previously presented) The oral dosage form of claim 29, wherein said opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephene, cyclazocine, levallorphan, pharmaceutically acceptable salts thereof, and mixtures thereof.

Claim 31. (Previously presented) The oral dosage form of claim 29, wherein either or both the opioid agonist and the acetaminophen would be subtherapeutic if not used in combination with each other.

Claim 32. (Previously Presented) A method of treating pain, comprising administering an

oral dosage form according to claim 1 orally to a human patient in an analgesically effective amount.

Claims 33-34 (Cancelled)

Claim 35. (Previously presented) The method of claim 32, wherein said oral dosage form further comprises a sustained release carrier such that the dosage form is administrable on a twice-a-day or on a once-a-day basis.

Claim 36. (Previously presented) The method of claim 32, wherein the amount of acetaminophen included in the dosage form is from about 10 mg to about 2000 mg.

Claim 37. (Previously presented) The method of claim 35, wherein the sustained release carrier causes said opioid agonist to be released over a time period of about 12 hours when orally administered to a human patient.

Claim 38. (Previously presented) The method of claim 35, wherein the sustained release carrier causes said opioid agonist to be released over a time period of about 24 hours when orally administered to a human patient.

Claim 39. (Previously presented) The method of claim 37, wherein the sustained release carrier causes said opioid antagonist to be released over a time period of about 12 hours when orally administered to a human patient.

Claim 40. (Previously presented) The method of claim 38, wherein the sustained release carrier causes said opioid antagonist to be released over a time period of about 24 hours when orally administered to a human patient.

Claim 41. (Previously presented) An oral dosage form, comprising an orally therapeutically effective amount of

(A) an opioid agonist,

(B) acetaminophen, and

(C) an opioid antagonist; the dosage form having a ratio of opioid antagonist to opioid agonist to acetaminophen that provides a combination product which is analgesically effective when the combination is administered orally, but which (i) is aversive in physically dependent human subjects when administered in the same amount as said therapeutically effective amount; and (ii) maintains an analgesic effect but does not increase analgesic efficacy of the opioid agonist together with the acetaminophen relative to the same therapeutic amount of opioid analgesic together with the acetaminophen when administered to human patients without said opioid antagonist.

Claim 42 (Previously presented) The oral dosage form of claim 1, wherein the antagonist included in the oral dosage form causes an aversive experience in a physically dependent addict taking about 2 to 3 time said therapeutically effective amount.

Claim 43 (Previously presented) The oral dosage form of claim 1, further comprising one or more pharmaceutically acceptable inert excipients.

Claim 44 (Previously presented) The oral dosage form of claim 1, further comprising an additional non-opioid drug selected from the group consisting of an NSAID, an NMDA receptor antagonist, a drug that blocks a major intracellular consequence of NMDA-receptor activation, dimenhydrinate or a pharmaceutically acceptable salt thereof, and antitussive, an expectorant, a decongestant, and antihistamine, and mixtures thereof.

Claim 45 (Previously presented) A method of treating pain, comprising administering an oral dosage form according to claim 41 orally to a human patient in an analgesically effective amount.

III. REMARKS

Reconsideration of the present application is respectfully requested.

Reconsideration of this application in view of the following remarks is respectfully requested. Claims 1, 3, 8-10, 12-27, 29-32, and 35-45 are currently pending.

A. Double Patenting Rejection

In the Advisory Action, the Examiner continue to reject claims 1, 3, 8-10, 12-27, 29-32, and 35-45 under 35 U.S.C. 101 on the grounds that "Applicants' claims are directed to the identical dosage form and method of treatment as in the US 6,375,957 B1 reference, Kaiko et al. ... Claim 1 of the reference and claim 1 of the application are both directed to the identical dosage form, an oral dosage form ... The elements are identical and the properties exhibited by the dosage form would inherently be the same ..."

This reference is respectfully traversed. It is respectfully submitted that the claims of the Kaiko reference do not claim the same oral dosage form as recited in the present claims.

Claim 1 of the present application recites ". . . . a combination product which is analgesically effective when the combination is administered orally, but which (i) is aversive in physically dependent human subjects when administered in the same amount **and** in a higher amount than said therapeutically effective amount . . . ." (emphasis added).

In contrast, independent claim 1 of U.S. Patent No. 6,375,957 recites " . . . . a combination product which is analgesically effective when the combination is administered orally, but which (i) is aversive in physically dependent human subjects when administered in the same amount **or** in a higher amount than said therapeutically effective amount . . . ." (emphasis added).

In order to infringe claim 1 of the present application, a dosage form must be "aversive in physically dependent human subjects when administered in the same amount **and** in a higher amount than said therapeutically effective amount. In order to infringe claim 1 of the Kaiko reference, a dosage form must be aversive in physically dependent human subjects when administered in the same amount **or** in a higher amount than said therapeutically effective amount.

Accordingly a dosage form which **is** aversive in physically dependent human subjects when administered in a **higher** amount than the therapeutically effective amount and which **is not** aversive in physically dependent human subjects when administered in the **same** amount than the therapeutically effective amount **would** infringe claim 1 of the Kaiko reference but **would not** infringe present claim 1. Therefore, claim 1 does not define identically the same invention as the Kaiko reference and the statutory double patenting rejection should be removed.

Further, claim 41 of the present application recites ". . . . a combination product which is analgesically effective when the combination is administered orally, but which (i) is aversive in physically dependent human subjects when administered **in the same amount** as said therapeutically effective amount . . . ." (emphasis added).

Accordingly a dosage form which **is** aversive in physically dependent human subjects when administered in a **higher** amount than the therapeutically effective amount and which **is not** aversive in physically dependent human subjects when administered in the **same** amount than the therapeutically effective amount **would** infringe claim 1 of the Kaiko reference but **would not** infringe present claim 41. Therefore, claim 41 does not define identically the same invention as the Kaiko reference and the statutory double patenting rejection should be removed.

Applicants note that the above arguments with respect to claim 1 of U.S. Patent No. 6,375,957; are also applicable to claims 32, 54, and 55 of U.S. Patent No. 6,375,957.

In view of the above remarks, the Examiner is respectfully requested to withdraw the double patenting rejection under 35 U.S.C. 101.